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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/912,122	07/24/2001	Joshua Makower	TRNSV-015G	4515

7590 03/17/2005

MEDTRONIC VASCULAR, INC.  
IP LEGAL DEPARTMENT  
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SANTA ROSA, CA 95403

EXAMINER

ISABELLA, DAVID J

ART UNIT PAPER NUMBER

3738

DATE MAILED: 03/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/912,122

Applicant(s)

MAKOWER ET AL.

Examiner

DAVID J ISABELLA

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 December 2004.  
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 53-58 and 61-63 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 53-58 and 61-63 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_\_.

### ***Status of the Claims***

A request for continuing examination was filed by the applicant on September 13, 2004. Amendment filed concurrently cancels claims 1-52 and adds new claims 53-63. The prosecution history of the previous claims was directed to elected embodiment of Figure 2 (original claims 5-11). Applicant made the election without traverse on September 13, 2003.

### ***Specification***

A substitute specification excluding the claims is required pursuant to 37 CFR 1.125(a) because pages 35,38 and 39 are missing.

A substitute specification must not contain new matter. The substitute specification must be submitted with markings showing all the changes relative to the immediate prior version of the specification of record. The text of any added subject matter must be shown by underlining the added text. The text of any deleted matter must be shown by strike-through except that double brackets placed before and after the deleted characters may be used to show deletion of five or fewer consecutive characters. The text of any deleted subject matter must be shown by being placed within double brackets if strike-through cannot be easily perceived. An accompanying clean version (without markings) and a statement that the substitute specification contains no new matter must also be supplied. Numbering the paragraphs of the specification of record is not considered a change that must be shown.

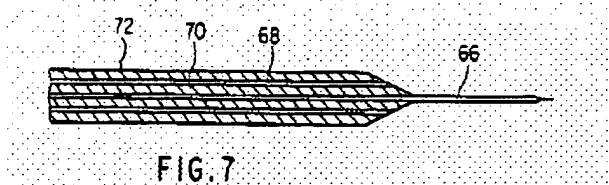
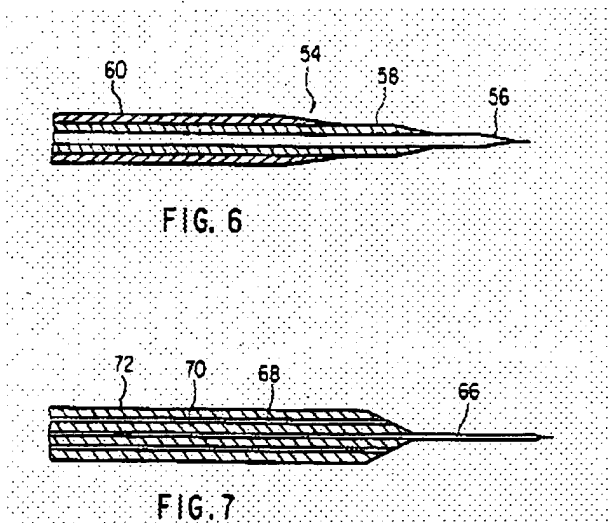
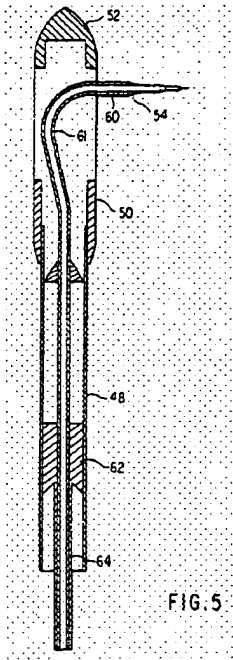
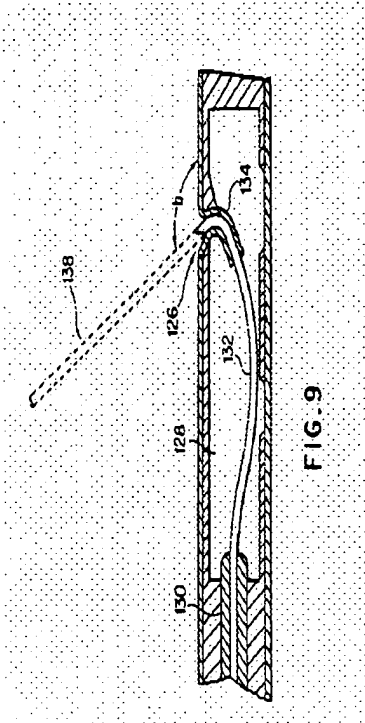
***Applicant alleges that a substitute specification that complies with 37 C.F.R. 1.125(a) was submitted with applicant's response filed on 12/27/2004. However, there is no record of the specification having been filed..***

***Claim Rejections - 35 USC § 102***

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 53,58, are rejected under 35 U.S.C. 102(b) as being anticipated by Edwards, et al (5366490).

Edwards et al discloses a guide device (124) that is useable to guide the advancement of a guidewire (56 or 66), said device comprising: a elongate catheter body having at least one lumen (128) extending longitudinally therethrough; an opening (134) formed in said catheter body; and, a tubular member (138,72 or 60) having a lumen and a distal end opening, said tubular member being alternately disposable in; a) a retracted position wherein the tubular member is substantially within the catheter body; and b) an extended position wherein the tubular member assumes a curved configuration and extends out of the opening such that a guidewire may be advanced though the lumen of the tubular member and out of the distal end opening of the tubular member. (See figures 5-11)



***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

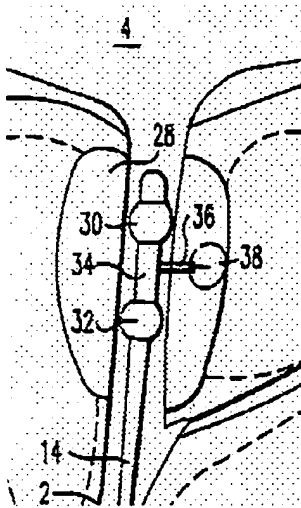
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 54,55,61,62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards et al (45366490) as applied to claim 53 above, and further in view of Shturman (5331947).

An imaging device comprising an anchoring member (30,32) being deployable when the catheter body is inserted into an anatomical lumen such that a surface of the balloon anchoring member will engage a wall of the anatomical lumen thereby preventing at least a portion of the catheter body from undergoing substantial movement within the anatomical lumen. While it is not clear if the probe of Edwards, et al is external to the catheter or disposed internally within the lumen. Shturman teaches placement of the ultrasound transducer internal to the lumen for imaging the same. If not inherent in Edwards, et al to place the imaging device internally of the lumen along with the combination of a balloon anchor/imaging means, so that the surgeon can precisely place and anchor the probe at the predetermined/selected location in vivo would have been obvious to one with ordinary skill in the art at the time of the invention thereof. Precise location and anchoring the probe to that location offers the surgeon better means for obtaining clear imaging resolution of the selected location.

Claims 54 and 55, the balloon anchoring member is shown in figure 2 .

Claims 61,62, see description for figure 15, column 3, lines 60+ and column6, lines 50+.



Claims 56,57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards et al (45366490) in view of Shturman (5331947) as applied to claim 54 above, and further in view of Abele (6010480).

Examiner has applied Abele et al as a secondary teaching for increasing the frictional surface of a balloon catheter for increasing the engaging forces of the balloon to an adjacent luminal structure. It would have been obvious to one with ordinary skill in the art to provide the outer surface of the balloon with frictional components to increase the engaging forces of the outer surface of the balloon to adjacent luminal structures.

Claim 63 is rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards et al (45366490) in view of Shturman (5331947) as applied to claim 54 above, and further in view of Seward et al (5345940).

To modify the single lumen catheter of Edwards, et al to a multi-lumen catheter system capable of employing multiple tools via a single catheter thereby reducing the need for multiple independent catheters, would have been obvious to one with ordinary skill in the art in view of the teachings of Seward, et al. See columns 7 and 8 for claim 59.

### ***Conclusion***

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

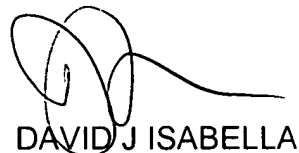


shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID J ISABELLA whose telephone number is 703-308-3060. The examiner can normally be reached on MONDAY-FRIDAY.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, CORRINE MCDERMOTT can be reached on 703-308-2111. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



DAVID J ISABELLA  
Primary Examiner  
Art Unit 3738

DJI  
March 15, 2005